REMARKS

Favorable reconsideration is respectfully requested in view of the following remarks. Claims 1-2, 4-11 and 13-30 are pending.

Claim rejections - 35 U.S.C. § 103

Claims 1, 2, 4-11 and 13-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP1 002874 A2 (Komori et al.) in view of Eur. J. Biochem., 1996, Vol. 242, pp. 499-505 (Yoshida et al.) and US Patent No. 6,127,138 (Ishimaru et al.) and further in view of Biochemistry, 1988, Vol. 27, pp. 5470-5476 (Montellano et al.) and of US Patent No. 5,556,788 (Kwan et al.) and of J. Nutr., 1982, Vol. 112, p. 1631-1637 (Fry et al.). Applicants respectfully traverse this rejection.

Applicants submit that there would not have been a reasonable expectation of success in combining the cited references and achieving the feature of adding a degradation FAOD to the sample as a pretreatment so that a free amino acid that is glycated present in the sample as a contaminant is degraded and removed from the sample by the degradation FAOD and the analyte remains in the sample, as recited in claim 1, in a method that uses the amount of hydrogen peroxide generated by the FAOD for the measurement of the glycated protein.

In particular, the method of claim 1 is related to a method of measuring an amount of glycated protein, where the glycated protein is degraded by a protease to generate glycated peptide and/or glycated amino acid, and the glycated peptide and/or glycated amino acid is degraded by FAOD to generate hydrogen peroxide. The amount of hydrogen peroxide generated is determined to be the amount of the glycated protein. It is generally accepted that FAOD is used to produce hydrogen peroxide, where the produced amount of hydrogen peroxide corresponds to the amount of the glycated protein to be measured. It is also generally accepted that producing hydrogen peroxide from glycated peptide and glycated amino acid other than those from the degraded product of glycated protein should be avoided, since hydrogen peroxide generated from glycated peptide and glycated amino acid other than those from the degraded product of glycated protein would disrupt the accuracy of the measurement of the glycated protein. The cited references do not provide any guidance or experimental data to show that FAOD, which is known to generate hydrogen peroxide in the presence of glycated peptide and glycated amino acid, can be used in a pretreatment to

degrade and remove free amino acid that is glycated, in a method where FAOD is used to measure the amount of the hydrogen peroxide generated from the degradation product of the glycated protein.

Specifically, Komori discloses a method where FAOD is used to measure the amount of the hydrogen peroxide generated from the degradation product of the glycated protein (paragraphs 0002-0004 and 0029-0030 of Komori). Komori does not teach adding a degradation FAOD to the sample as a pretreatment so that a free amino acid that is glycated present in the sample as a contaminant is degraded and removed from the sample by the degradation FAOD and the analyte remains in the sample, as recited in claim 1.

Yoshida, Ishimaru, Kwan, Montellano and Fry do not remedy the deficiencies of Komori. In particular, Yoshida also discloses a method where FAOD is used to measure the amount of the hydrogen peroxide generated from the degradation product of the glycated protein (see under Analyses in column 2 on page 500 of Yoshida), and likewise does not teach or suggest that a degradation FAOD can be used as a pretreatment to degrade and remove free amino acid that is glycated, as recited in claim 1, in a method that uses the amount of hydrogen peroxide generated by the FAOD for the measurement of the glycated protein.

Monteallano teaches that in the case of catalase, the coordination of the azide anion to the prosthetic heme iron atom inhibits the catalytic dismutation of hydrogen peroxide (see column 1 on page 5470 of Montellano). Kwan teaches the use of a tetrazolium salt that reacts with fructosamine for the determination of fructosamine (see column 2 of Kwan). Montellano and Kwan are far from teaching or suggesting adding a degradation FAOD to the sample as a pretreatment so that a free amino acid that is glycated present in the sample as a contaminant is degraded and removed from the sample by the degradation FAOD and the analyte remains in the sample, as recited in claim 1.

As to Fry, the rejection appears to contend that since Fry teaches the formation of free amino acids that are glycated in nutritional solutions used for intravenous feeding, and that these products can enter circulation of the patients infused with these solutions during intravenous feeding, it would have been obvious to use the degradation FAOD to degrade the free amino acid that is glycated in a method where FAOD is used to measure the amount of the hydrogen peroxide generated from the degradation product of the glycated protein. However, Fry likewise does not provide any reason to expect that an FAOD could be used in

a pretreatment to degrade and remove free amino acid that is glycated in a method that uses the amount of hydrogen peroxide generated by the FAOD for the measurement of the glycated protein. Accordingly, claim 1 and its dependent claims are patentable over the references for at least these reasons.

Claim 1 further recites that the redox reaction is conducted in the presence of a tetrazolium compound and sodium azide. By adding the tetrazolium compound and sodium azide, the sensitivity becomes about 1.2 to 3 times greater than in the case where they are not added (see page 23, lines 9-12 of the present specification).

Komori, Ishimaru, Montellano and Fry are silent as to the combined use of a tetrazolium compound and sodium azide. Although Kwan mentions that sodium azide can be added in their system for measuring fructosamine, Kwan is directed to a completely different method using completely different components for the measurement of their analyte. Nothing in the references teaches or suggests the combined use of tetrazolium compound and sodium azide in a method that uses the amount of hydrogen peroxide generated by the FAOD for the measurement of the glycated protein, as recited in claim 1 or the benefits. Accordingly, the references are further removed from claim 1 and its dependent claims.

Claim 9 is directed to a measuring kit used for measuring a glycated protein using a FAOD. Claim 9 recites that the first FAOD is present in an amount suitable for a degradation of a free amino acid that is glycated present in the sample as a contaminant. As is clear from the discussion above, there would not have been a reasonable expectation of success in combining the cited references and obtaining a first FAOD that is present in an amount suitable for a degradation of a free amino acid that is glycated present in the sample as a contaminant. Accordingly, claim 9 and its the dependent claims are patentable over the references, taken alone or separately.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

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